

Maryland Board of Pharmacy
Public Board Meeting

Agenda
Date: October 17, 2012

Name	Title	Present	Absent	Present	Absent
Board Committee					
Bradley-Baker, L.	Commissioner/Treasurer				
Chason, D.	Commissioner				
Finke, H.	Commissioner				
Gavgani, M. Z.	Commissioner				
Hammonds, S.	Commissioner				
Handelman, M.	Commissioner				
Israbian-Jamgochian, L.	Commissioner				
Matens, R.	Commissioner				
Souranis, M.	Commissioner//President				
St. Cyr, II, Z. W.	Commissioner				
Taylor, D.	Commissioner				
Taylor, R.	Commissioner/Secretary				
Board Counsel					
Bethman, L.	Board Counsel				
Felter, B.	Staff Attorney				
Board Staff					
Naesea, L.	Executive Director				
Wu, Y.	Compliance Manager				
Daniels, D	Licensing Manager				
Gaither, P.	Administration and Public Support Manager				
Jeffers, A.	Legislation/Regulations Manager				
Kolapalli, P	MIS Project Manager				

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
I. Executive Committee Report(s)	A. M. Souranis, Board President B. R. Taylor Secretary	<p><i>Members of the Board with a conflict of interest relating to any item on the agenda are advised to notify the Board at this time or when the issue is addressed in the agenda.</i></p> <ol style="list-style-type: none"> 1. Call to Order 2. Sign-in Introduction and of meeting attendees – <i>(Please indicate on sign-in sheet if you are requesting CE Units for attendance)</i> 3. Distribution of packet materials 4. Review and approve September 19, 2012 Minutes Draft Public Minutes 09-19-2012 	
II. Executive Director Report	A. L. Naesea	<ol style="list-style-type: none"> 1. Operations Update 2. Meeting Updates: -NABP District Meeting update 3. Other – Reminder that November Board Meeting will be held on 4th Wednesday, November 28, 2012 	
B. Administration and Public Support	B. P. Gaither, Manager	<ol style="list-style-type: none"> 1. Personnel Updates - Vacancies and Recruits 2. Contracts and Procurement 	

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C. MIS	P. Kolapalli, MIS Project Manager	<p>Accomplishments:</p> <ol style="list-style-type: none"> 1. Maryland Board of Pharmacy recently implemented a much awaited new automation system as of October 1, 2012 but, the eGov portion (the public domain) was not able to fully be operational until October 5, 2012. 2. In addition to Pharmacists, the new system will now allow Pharmacy Technicians, Pharmacies and Wholesale Distributors to renew on-line. 3. As of October 10, 2012, we received over <u>seventy (70)</u> online payment transactions, which include Pharmacists and Technicians renewals. 4. The Board is accepting all credit card types; VISA, DISCOVER and AMERICAN EXPRESS. 5. We are working with SA vendor on the final system roll-out activities (trainings, deliverables, etc.) as per the contract and we are currently into the one-year "Premium Maintenance" contract. 6. Pharmacy Board also facilitated a demo session about the compliance of the new automation system to DHMH auditor before the program went live. 7. We extended employment offer and will have a new MIS Project Manager who is starting by end of 	

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		<p data-bbox="768 230 936 256">October 2012.</p> <p data-bbox="625 329 709 355"><u>Issues:</u></p> <ol data-bbox="720 396 1398 841" style="list-style-type: none"> <li data-bbox="720 396 1398 493">1. Several issues were identified by BOP staff after the go-live and we are working with SA vendor resolving the issues based on the priorities in a timely fashion. <li data-bbox="720 526 1398 623">2. There are no show stoppers, all the issues are being tracked and managed according to the formal procedure. <li data-bbox="720 656 1398 753">3. We are expecting automation suite (for licensing, accounting and compliance units) to be fully operational in the week of 10/22/2012. <li data-bbox="720 786 1398 841">4. Overall, the project is on schedule and under budget working towards fully operational. <p data-bbox="625 906 1220 932">As a part of Continuous Process improvements:</p> <ol data-bbox="720 972 1398 1370" style="list-style-type: none"> <li data-bbox="720 972 1398 1078">1. BOP is compiling the new requirements for automation enhancements as part of Phase II implementation by Winter 2012 <li data-bbox="720 1110 1398 1192">2. BOP is working with NABP and Tax Comptroller's office establishing the data exchange by Winter 2012 <li data-bbox="720 1224 1398 1370">3. BOP is working with on outsourcing the Data Management services, scanning and achieving the 100-year old Pharmacy paperwork in the back office by winter 2012. 	

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D. Licensing	D. Daniels, Manager	1. Licensing Unit Update 2. Monthly Statistics	
E. Compliance	Y. Wu, Manager	1. Monthly Statistics 2. PEAC Update	
F. Legislation & Regulations	A. Jeffers	<p><u>MEETINGS:</u></p> <p><u>1)</u></p> <p><u>1) September 24th meeting regarding the increase in the dispensing fee regulations for Dentists, Physicians and Podiatrists. Fran Phillips, Marie Grant, Board Execs and Jennifer Newman.</u></p> <p>DDC will send an initial letter to dispensing prescribers to describe the new law and request that dispensing prescribers notify their respective boards if they no longer want to have a dispensing permit.</p> <p><u>LEGISLATION:</u></p> <p><u>Meetings are being scheduled to meet with Chairman Hammen and Chairman Carter Conway</u></p> <p><u>LEGISLATIVE REPORTS</u></p> <p>1) Maryland Board of Pharmacy Wholesale Distributor Permitting and Prescription Drug Integrity Act Sixth Annual Report to the Governor and the General Assembly</p> <p>Board approval requested for the Sixth Annual Wholesale</p>	

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		<p>Distributor Report.</p> <p><u>FINAL DRAFT - Report WholesaleDist Program 092612</u></p> <p><u>2) Report on the Implementation and Use of Sanctioning Guidelines as required by Chapters 533 and 534 of the Act of the General Assembly of 2010</u></p> <p><u>FINAL Report to EHEHGO on Sanctioning Guidelines 101712</u></p> <p><u>REGULATIONS:</u></p> <p>10.34.03 – Inpatient Institutional Pharmacies –Under consideration by the Practice Committee.</p> <p>10.34.06 Reporting Pharmacist’s and Pharmacy Technician’s Mailing Address and Location of Employment</p> <p>Board approval requested to add pharmacy technician’s to this chapter</p> <p><u>DRAFT 10.34.06 100312</u></p> <p>10.34.11 - Disciplinary Monetary Penalties, and Civil Fines</p> <p>Published August 24, 2012. Two official comments received:</p> <p><u>Formal Comment - MPhA – 092412</u></p>	

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		<p><u>Formal Comment 10.34.11 omnicare com</u></p> <p><u>Draft Bd Response – 10.34.11 – MPHA</u></p> <p><u>Draft Bd Response – 10.34.11 – MACDS</u></p> <p>Board approval requested for responses to the comments and to adopt the revisions as proposed.</p> <p>Additionally, would the Board like an effective date as soon as possible or is a delayed timeframe requested for implementation?</p> <p>10.34.14 – Opening and Closing of Pharmacies and 10.34.30 – Change to Permit – Pharmacy or Distribution Permit Holder.</p> <p>Proposal released for informal comment 9/25/12 through 10/12/12. Comments to be considered at the 10/31/12 Practice Committee Meeting.</p> <p>10.34.22 – Licensing of Wholesale Prescription Drug or Device Distributors –</p> <p>Three Informal Comments received.</p> <p><u>Informal Comment from Utah Medical</u></p> <p><u>Another informal comment from Utah Medical 091012</u></p> <p><u>Informal comment -Jennifer Schneider - State Licensing Services</u></p> <p><u>Maryland.gov Mail - Re Release for INFORMAL COMMENT - Chandra Mouli 082112</u></p> <p>Board approval requested for template response to the informal</p>	

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		<p>comments:</p> <p><u>Draft Bd Response for Inform Cmts Wholesale Dist - Utah 100112</u></p> <p><u>Draft Bd Response for Inform Cmts Wholesale Dist - SLS 100112</u></p> <p><u>Draft Bd Response for Inform Cmts Wholesale Dist - DDC 100112</u></p> <p>Board approval requested for revisions to COMAR 10.34.22 as a result of the informal comments.</p> <p><u>FINAL DRAFT 10.34.22 092612</u></p> <p>10.34.29 – Drug Therapy Management</p> <p><u>Holding for Board of Physician’s approval of the proposal.</u></p> <p>10.34.33 – Holding for Fed Regs .</p> <p>10.34.36 – Pharmaceutical Services to Residents in Assisted Living Programs and Group Homes - Published September 21, 2012. Holding for expiration of 30 day comment period.</p> <p>10.13. 01 – Dispensing of Prescription Drugs by a Licensee</p> <p>Under consideration by the Practice Committee.</p>	

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III. Committee Reports A. Practice Committee	H. Finke, Chair,	<p>1)Michelle McGovern, lawyer</p> <p><u>12-403(f)(6) phone hours for the 6th day</u></p> <p><u>Draft Bd Response – Nonresident – phone hrs for 6th day</u></p> <p>2) Dr. Jennifer Gudeman, Ther-Rx Corporation</p> <p><u>Compounding of hydroxyprogesterone caproate injections</u></p> <p><u>Draft Bd Response – Compounding – Hydroxyprogesterone</u></p> <p><u>3) Two phone calls concerning how long a pharmacist, working at a nonresident pharmacy who is in the reciprocity process, has to take the MPJE wants approved to take the exam.</u></p> <p>As long as the pharmacist exercises due diligence in taking the MPJE as soon as possible, there is no specific timeframe in which the pharmacist has to take the exam.</p> <p><u>Draft Bd Response - SB 132 - timeframe for MPJE</u></p> <p>4) Dr. Yunus Thakur</p> <p><u>RFID tagging</u></p> <p><u>Draft Bd Response – RFID tagging</u></p>	

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B. Licensing Committee	D. Chason Chair,	<p>1) Review of Pharmacist Applications: None</p> <p>2) Review of Pharmacy Technician Applications:</p> <ul style="list-style-type: none"> • <u>Kathleen Harding</u> - Applicant answered yes to question # 3 regarding surrendering or failing to renew a healthcare registration or license. Explanation: Choose not to renew her DE Nursing Assistant registration. Says she was no longer able to fulfill duties of her job. Recommendation is to approve application. <p>3) Review of Distributor Applications: NONE</p> <p>4) Review of Pharmacy Technicians Training Programs:</p> <ul style="list-style-type: none"> • Pharmacy Technican University from Pharmacist Letter – Recommendation is to approve program. <p>5) New Business:</p> <ul style="list-style-type: none"> • <u>Donald Richard</u> - Licensee would like a refund of the renewal fees paid as he was unable to renewal online. Applicant sent in letter stating he choose not to renew and requested his license to be placed on an inactive status, but attached his CE's and renewal fee, but no application. Information was processed and letter was sent to applicant requesting additional CE's. Recommendation is to deny refund request as it is an administrative fee. • Letter from <u>Respicare</u> requesting waiver for having a MD licensed pharmacist on staff and an email from <u>Rossanna Cielo</u> with the same request. Recommendation is to write letter stating the Board's current interpretation on companies that sell prescription devices to individuals in their home being required to be a pharmacy. 	

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		<p>Dupaco, Inc – Company would like to verify that Md Board of Pharmacy’s laws regarding wholesale distributors applies to them. Recommendation is to ask company to provide documentation that device isn’t a prescription and to contact their attorney to determine legality of labeling a product as “prescription only” when the FDA has not approved it.</p> <ul style="list-style-type: none"> • Drug Therapy Management Application – Recommendation is to approve application. • Sub-Committee Recommendation - Licensing Committee recommendation to develop a sub-committee of Licensing and Practice to involve Office of Healthcare Quality, Board of Pharmacy and OHCQ in regulatory changes that need to be made on whether or not it makes sense to require DME companies that dispense only a few prescription devices to be pharmacies 	
C. Public Relations Committee	L. Bradley-Baker, Chair	Public Relations Committee Update- <ul style="list-style-type: none"> • Baby Boomer Expo Update • Community Outreach update 	
D. Disciplinary	L. Israbian-Jamgochian Chair	Disciplinary Committee Update-	
E. Emergency Preparedness Task Force	D. Taylor Chair	Emergency Preparedness Task Force Update- No update for October, 2012	
F. Drug Therapy Management	Rodney Taylor, Lynette Bradley-Baker	Joint Committee Update – <ul style="list-style-type: none"> • See Licensing Committee report above which 	

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	Co-Board Representatives	recommends approval of new DTM application	
IV. Other Business & FYI	M. Souranis, Board President	None	
V. Adjournment	M. Souranis, Board President	<p>The Public Meeting was adjourned at _____.</p> <p>At _____ P.M. M. Souranis convened a Closed Public Session to conduct a medical review of technician applications.</p> <p>C. The Closed Public Session was adjourned at _____ P.M. Immediately thereafter, M. Souranis convened an Administrative Session for purposes of discussing confidential disciplinary cases. With the exception of cases requiring recusals, the Board members present at the Public Meeting continued to participate in the Administrative Session.</p>	